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IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

GENOMIC HEALTH, INC.,

Plaintiff and Counter-Defendant,

v.

INCYTE CORPORATION,

Defendant and Counter-Claimant.

No. 10-CV-03643 JSW

JOINT CASE MANAGEMENT STATEMENT AND RULE 26(f) REPORT

Date: December 17, 2010
Time: 1:30 pm
Courtroom 11, 19th Floor

Hon. Jeffrey S. White

Pursuant to the Court's October 4, 2010, Order Setting Case Management Conference and Requiring Joint Case Management Conference Statement, Federal Rules of Civil Procedure 26(a) and (f), Local Rule 2-1, 16-9, and this Court's Civil Standing Order, counsel for Plaintiff Genomic Health, Inc. ("Genomic Health") and Defendant Incyte Corporation ("Incyte") have conferred regarding a discovery plan in this matter, the nature and basis of their respective claims and defenses, and the possibility of settlement. In accordance therewith, the parties submit this Joint Case Management Statement and Joint Rule 26(f) Report ("CMC Statement").

I. JURISDICTION AND SERVICE

Pursuant to this Court's Order of November 10, 2010, Denying Genomic Health's Motion to Remand, the Court has determined that it has subject matter jurisdiction over the entire action pursuant to 28 U.S.C. §§ 1331 and 1338. The parties do not contest personal jurisdiction over them for purposes of this action. The parties further do not contest venue for purposes of this action.

All parties have been served.

II. BACKGROUND OF DISPUTE AND STATEMENT OF FACTS

A. PLAINTIFF'S STATEMENT OF FACTS

Genomic Health is a Redwood City based life science company founded in August 2000 and committed to improving the quality of cancer treatment decisions through genomics-based clinical laboratory services. The company currently offers molecular diagnostics for breast and colon cancer patients.

Genomic Health has developed the Onco*type* DX® Breast Cancer Assay, which predicts the likelihood that a patient with early-stage, ER-positive breast cancer will experience a recurrence within 10 years and whether that patient will benefit from adding chemotherapy to hormonal therapy. The selection and validation of Oncotype DX genes required thousands of research hours. Genomic Health has received multiple patents covering the elucidation of this valuable genomic information in exchange for making all of its cancer biomarkers, assay platform technology, and validation study data public.

In or about January 2004, Genomic Health commenced commercial marketing of the Onco*type* DX® Breast Cancer Assay. Genomic Health's Onco*type* DX® Breast Cancer Assay is a test which measures for the presence of the expression of portions of certain genes, and then correlates those expression levels to give information about the patient's individual disease state.

One portion of the genes that are measured in the Onco*type* DX® Breast Cancer Assay is a portion of a gene known as the CTSL2 gene, which encodes for a protein known as the Cathepsin L2 protein. The CTSL2 gene is expressed in breast carcinomas but not in normal mammary gland tissues. The Genomic Health Onco*type* DX® Breast Cancer Assay detects a certain limited portion of the CTSL2 gene sequence. This limited portion of CTSL2, known as the "amplicon sequence," comprises 67 nucleotides within the CTSL2 gene and does not comprise a DNA encoding for a Cathepsin having cysteine protease activity, which the licensed '606 Patent requires.

Genomic Health independently developed the Oncotype DX® Breast Cancer Assay utilizing public domain information. For example, the sequence for human CTSL2 was published as early as 1998. (*See* W. Adachi, et al., Inves. Opthamol. Vis. Sci. 39(10):1789-1796 (1998); R. Itoh, DNA Res. 6(2):137-140 (1999)). Further, the relevance of cathepsins to human breast cancer was also in the public domain, including breast cancer microarray studies conducted by Rosetta Inpharmatics. (*See*, *e.g.*, L. van't Veer, et al., Nature 415:530-536 (2002); M.J. van de Vijver, et al., NEJM 347:1999-2009 (2002).) The RNA primers and probes for a certain limited portion of CTSL2 were designed based on public information available in NCBI GenBank. (*See* GenBank Accession No. NM_001333, which does not have an identical sequence as the sequences claimed for CTSL2 in Incyte's '606 or '893 patents, *infra*.)

On or about March 30, 2001, Genomic Health and Incyte entered into the LifeSeq Agreement. Previously, three written amendments to the LifeSeq Agreement were entered into respectively on December 21, 2001, July 19, 2002, and October 25, 2004. Under the terms of the LifeSeq Agreement, Genomic Health obtained non-exclusive licenses to discover, develop, make, have made, use, offer to sell, sell, import, and distribute Personalized Research product(s) in the Personalized Research Field of Use under a Valid Claim of Defendant's Licensed Patents. For

any particular product, Genomic Health was obligated to pay certain milestone and royalties for each product "under the respective license(s) as applicable."

On or about September 16, 2003, U.S. Patent No. 6,620,606 ("'606 patent") issued, naming Defendant as the Assignee, and was thereby licensed under the LifeSeq Agreement. However, the published '606 Patent sets forth patent claims not actually allowed by the United States Patent and Trademark Office. According to the prosecution history for the '606 Patent, Defendant narrowed all pending claims to include the limitations of "Cathepsin having cysteine protease activity" or "Cathepsin" and further canceled then pending claim 30, and based upon these amendments and cancellations, the Examiner allowed the pending claims. The published '606 Patent failed to reflect these amendments narrowing the scope of the claims, and the '606 Patent published with the unamended claims.

In addition to not informing Genomic Health of the change in the scope of the license under the LifeSeq Agreement by this mistake in the Patent Office, Defendant failed to pay the maintenance fee due on September 16, 2007, for the '606 Patent, and six months thereafter, the '606 Patent lapsed, relieving any contractual obligation under the LifeSeq Agreement to pay a royalty for that licensed patent. Defendant never informed Genomic Health that the '606 Patent had lapsed, and Genomic Health was unaware the '606 Patent had lapsed.

On or about April 13, 2004, Genomic Health sent to Defendant a milestone payment of $100,000 under the LifeSeq Agreement for the Onco*type* DX® Breast Cancer Assay under the mistaken belief that the licensed, but incorrectly published, '606 Patent potentially covered the CTSL2 gene sequence portion used in the Onco*type* DX® Breast Cancer Assay, and thus the $100,000 milestone payment for a Personalized Research Product was due under the LifeSeq Agreement. Genomic Health mistakenly commenced on June 29, 2004 quarterly royalty payments under the LifeSeq Agreement for commercial sales of the Onco*type* DX® Breast Cancer Assay as it misapprehended the license's scope due to the Patent Office mistake and the failure of Defendant to inform Genomic Health of the license's proper scope. Genomic Health made such payments up to March 1, 2010. The overpaid royalty payments not in fact due under the LifeSeq Agreement total $3,476,681.47.

When the correct facts came to Genomic Health's attention, it ceased further payments and demanded the return of amounts paid outside the proper scope of the LifeSeq Agreement. Defendant refused, and thus Genomic Health filed suit on July 8, 2010, in the Superior Court of the County of San Mateo, asserting a cause of action for money had and received and a cause of action for unjust enrichment.

B. DEFENDANT'S STATEMENT OF FACTS

Incyte is a Wilmington, Delaware-based drug discovery company whose mission is to develop and introduce advanced therapeutic treatments to patients suffering from diseases such as cancer, inflammation, and diabetes. From its inception until about December 2002, Incyte, then called Incyte Genomics, Inc., was a leading genomic-based information supplier. During this time, Incyte developed the LifeSeq Database, a gene sequence database which provided researchers with a comprehensive view of the entire human genome, comprised of proprietary information regarding full-length human genes and the proteins they encode. The more than 120,000 gene transcripts contained in the LifeSeq Database were used for the identification of research targets and the discovery and development of new drugs and diagnostics. Incyte used, licensed, and sold this information to many pharmaceutical and biotechnology companies to help them create more effective therapies. At the end of 2002, in pursuit of a broader mission, Incyte began its shift from a genomic-based information supplier to the fully integrated drug and development organization that it is today.

Genomic Health is in the business of developing and commercializing genomic-based diagnostic tests and services. In order to facilitate the research and development of genomic-based diagnostic tests and services, Genomic Health and Incyte entered into the LifeSeq Collaborative Agreement on or about March 20, 2001. The parties made three subsequent amendments to the LifeSeq Collaborative Agreement, dated December 21, 2001; July 19, 2002; and October 25, 2004 (collectively referred to as the "LifeSeq Agreement").

Under the LifeSeq Agreement, Genomic Health received substantial benefits. First, Genomic Health received a non-exclusive license to practice Incyte Patent Rights, as defined in the LifeSeq Agreement, without being sued or otherwise held liable for infringement. Second,

Genomic Health was given access to Incyte's LifeSeq Database Products, which contain genomic data including information relating to DNA/RNA sequences, single nucleotide polymorphisms, and the expression of genes in cancer cells as well as other genomic information. Third, Genomic Health received access to Incyte Know-How, as defined in the LifeSeq Agreement.

Pursuant to the LifeSeq Agreement, milestone and royalty payments "will accrue or become due or payable with respect to Product(s) which are covered by a Valid Claim of Incyte Patent Rights." LifeSeq Agreement, Amend. 3 at ¶ 15. Further, milestone and royalty payments "will accrue or become due or payable with respect to Product(s)… identified or discovered by a process which (i) utilizes a Gene which is covered by a Valid Claim of Incyte Patent Rights and (ii) where the use of such Gene for such identification or discovery would have constituted an infringement of Incyte Patent Rights but for licenses granted hereunder."[1] *Id*. Thus, under the terms of the LifeSeq Agreement, the obligation to pay royalty payments can attach under certain circumstances regardless of whether the relevant patent remains in force. Additionally, Section 4.2 of the LifeSeq Agreement provides that payments are due with respect to products covered by the license to Incyte Know-How.

Among the patents licensed to Genomic Health under the LifeSeq Agreement were U.S. Patent Nos. 6,620,606 ("the '606 patent") and 6,033,893 ("the '893 patent"), which claim inventions relating to the Cathepsin L2 gene (CTSL2).

In 2004, approximately three years after entering into the LifeSeq Agreement, Genomic Health marketed its first product, the Onco*type* DX® Breast Cancer Assay. Genomic Health's Onco*type* DX® Breast Cancer Assay measures the expression of 21 different genes in a tumor sample. The Cathepsin L2 gene, or CTSL2, is one of the 21 genes whose expression is measured by the Onco*type* DX® Breast Cancer Assay.

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[1] The citations are to Section 4.3 of the LifeSeq agreement as amended. Section 4.3 of the original LifeSeq Agreement contains virtually identical provisions. Specifically, Section 4.3 of the original LifeSeq Agreement states "The foregoing payments under Section 4.2 will accrue or become payable with respect to Product(s) which … (b) are covered by a Valid Claim of Incyte Patent Rights and/or which Product is identified or discovered by process which utilizes a Gene which is covered by a Valid Claim of Incyte Patent Rights." LifeSeq Agreement at § 4.3.

On or about April 13, 2004, Genomic Health made a milestone payment for the Onco*type* DX® Breast Cancer Assay pursuant to the LifeSeq Agreement without advising Incyte of the reason for making the payments other than that they were pursuant to the LifeSeq Agreement. That is, Genomic Health failed to tell Incyte that the Onco*type* DX® Breast Cancer Assay practiced a claim of the '606 patent. Moreover, Incyte does not know – and has no way of independently knowing – whether the Onco*type* DX® Breast Cancer Assay, was "identified or discovered by a process which . . . utilizes a Gene which is covered by a Valid Claim of Incyte Patent Rights . . . where the use of such Gene for such identification or discovery would have constituted an infringement of Incyte Patent Rights" but for the LifeSeq license. Nor does Incyte at this point know whether its licensed Know-How was used in the development of the assay. At this time, Incyte had hundreds of gene patents and patent applications, and it had no duty under the LifeSeq Agreement to inform Genomic Health about the status of any of them.

Genomic Health continued to make royalty payments for the Onco*type* DX® Breast Cancer Assay from about June 29, 2004, to about March 1, 2010, at which time it ceased making payments and demanded a refund of the payments it had made.

III. THE PRINCIPAL LEGAL ISSUES IN DISPUTE

The parties dispute the following legal issues and/or that as framed, such legal issues are properly before the Court:

1. Whether Genomic Health's Onco*type* DX® Breast Cancer Assay was outside the scope of licensed Incyte's patents as narrowed such that Genomic Health made a mistake of fact when making payments to Incyte under the LifeSeq Agreement between 2004 and March 2010;

2. Whether Genomic Health was or is obligated under the LifeSeq Agreement at any time between 2004 to present to pay royalties to Inctye;

3. Whether Incyte failed to perform under the LifeSeq Agreement by failing to inform Genomic Health of its narrowed patent claims;

4. Whether Genomic Health breached the LifeSeq Agreement by failing to inform Incyte of its belief that the Onco*type* DX® Breast Cancer Assay practiced a valid claim of the '606 patent;

5. Whether Genomic Health is fully relieved from its obligations under the LifeSeq Agreement due to Incyte's failure to maintain the '606 Patent;

6. Whether Genomic Health is entitled to a refund of some or all of the royalties paid to Incyte under the LifeSeq Agreement, and reasonable attorneys' fees and costs;

7. Whether the Onco*type* DX® Breast Cancer Assay or any other Genomic Health products developed between 2001 and present are covered by a valid claim of Incyte patent rights; were identified or discovered by a process which utilizes a gene that is covered by a valid claim of Incyte Patent Rights, or were developed using Incyte Know-How;

8. Whether Genomic Health breached the LifeSeq Agreement by ceasing to make royalty payments for the Onco*type* DX® Breast Cancer Assay after March 1, 2010 or otherwise failing to make required payments for any Genomic Health product;

9. Whether Incyte has alleged and maintains based upon proper Rule 11 inquiry that the dispute extends beyond Genomic Health's Onco*type* DX® Breast Cancer Assay; and

10. Whether Genomic Health has a continuing obligation to make royalty payments to Incyte under the LifeSeq Agreement.

IV. ANTICIPATED MOTIONS AND HEARINGS

Pending Motions. No pending motions are currently in front of the Court in this action.

Discovery Motions. The parties anticipate the use of discovery motions only as necessary to obtain responsive discovery.

Pre-Trial Motions. The parties anticipate filing motions for summary judgment. Genomic Health anticipates filing an early summary judgment motion as the abandonment of the '606 patent, the amount paid to Incyte by Genomic Health and the fact that the Patent Office published the incorrect claims are not in dispute.

V. AMENDMENT OF PLEADINGS

The parties do not contemplate adding any additional parties. The parties agree that the last day to amend the pleadings is May 1, 2011.

VI. EVIDENCE PRESERVATION

The parties have taken appropriate steps to preserve any and all evidence that may be of relevance to the issues in the present action.

VII. DISCLOSURES

The parties exchanged their initial disclosures pursuant to Fed. R. Civ. P. 26(a) on December 3, 2010.

VIII. DISCOVERY

The parties conducted their Rule 26(f) Conference on November 19, 2010**.**

Status of Discovery. The parties have initiated written discovery at this time. Incyte served its First Set of Requests for Production on Genomic Health on December 3, 2010, and Genomic Health served interrogatories, document requests and requests for admission on December 10, 2010.

Genomic Health contends as follows: Genomic Health believes that the case is ripe for expedited resolution, including expedited discovery. As alleged in the pleadings, the dispute centers on whether a gene in Genomic Health's Onco*type* DX® Breast Cancer Assay is covered by a Valid Claim of an Incyte Patent, or, as Incyte further contends, such a covered gene was used in the product's development. The parties' pleadings contend that other products are at issue. Specifically, Incyte has not alleged in its counterclaim that Genomic Health breached the LifeSeq Agreement by failing to pay royalties due on other products, such as the Onco*type* DX® Colon Cancer Assay. Genomic Health does not challenge validity. Thus, the issues as framed by the pleadings are narrow and lend themselves to streamlined and expedited resolution.

Incyte contends as follows: Incyte does not agree that the case can be handled in an expedited fashion. Substantial discovery will be required to determine the manner by which the Onco*type* DX® Breast Cancer Assay, the Onco*type* DX® Colon Cancer Assay and other Genomic Health products developed between 2001 and present were developed, including identification of any gene used for during development, and whether they are or were covered by a valid claim of Incyte patent rights. Only by answering those questions can the Court determine whether royalty payments are or were due.

Unless otherwise stated herein, the parties will follow the general rules and limitations on discovery as set forth in the Federal Rules of Civil Procedure, Civil Local Rules, Standing Orders and other orders issued by the Court in this matter.

Depositions. No depositions have been taken in this case to date. Genomic Health proposes **five (5) depositions** per side, not including depositions of experts. Incyte proposes **ten (10) depositions** per side, not including depositions of experts.

Interrogatories. The parties propose that each side serve no more than **twenty-five (25) interrogatories**, pursuant to Fed R. Civ. P. 33.

Scope of Anticipated Discovery. The subjects of information for Genomic Health to prove its claims and for Defendant to defend against these allegations and prove its affirmative defenses and/or counterclaims will be: the prosecution and maintenance of the '606 and '893 Patents, identification and use of gene sequences in the Onco*type* DX® Breast Cancer Assay; Genomic Health's use of the LifeSeq Database; payment of amounts under the LifeSeq Agreement; Incyte further contends that the scope of anticipated discovery further entails the development, composition and use of the Onco*type* DX® Colon Cancer Assay and all other Genomic Health products which have been developed or discovered between 2001 and present; and all financial records related to Genomic Health's products developed between 2001 and present. Genomic Health's position is that Incyte has made no allegation under Rule 11 in its counterclaim for breach of contract that such subject matter is at issue.

Electronically Stored Information. The parties agree to produce electronically stored information in single-page .tiff format.

Protective Order. The parties contemplate that a protective order governing the treatment of confidential information will be required. The parties expect to submit a stipulated protective order that is similar to the model Stipulated Protective Order of the Northern District of California, with various modifications.

Schedule. Proposed discovery and disclosure deadlines are set forth below in Section XVIII.

IX. CLASS ACTIONS

This action is not a class action.

X. RELIEF

Genomic Health seeks a judgment of relief from the obligations under the LifeSeq Agreement, for repayment from Incyte in the amount of $3,576,681.47 incorrectly paid for the Onco*type* DX® Breast Cancer Assay, or as may be adjusted according to proof, for interest on the sum as allowed by law, and for other relief as the Court may order.

Subject to what discovery shows to be the full extent and/or nature of the injuries Incyte has suffered and continues to suffer for Genomic Health's breach of the LifeSeq Agreement, Incyte seeks damages to compensate Incyte for all royalties accrued under the LifeSeq Agreement that have not been paid by Genomic Health, including all royalties owed on continued sales of the Onco*type* DX® Breast Cancer Assay. Incyte further seeks attorneys fees and costs and any further relief as the Court may deem just and proper.

XI. SETTLEMENT AND ADR

Genomic Health believes that this case may benefit from an early ADR discussion and has offered to Incyte to mediate through a private mediator, such as Magistrate Judge Infante of JAMS. Incyte is amenable to this position.

XII. CONSENT TO MAGISTRATE JUDGE

Incyte has declined to proceed before a Magistrate Judge. This case has been reassigned to the Honorable Jeffrey S. White.

XIII. OTHER REFERENCES

This case is not suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

XIV. NARROWING OF ISSUES

The parties will most likely file one or more dispositive motions seeking to narrow the issues in this case. Both parties anticipate filing one or more motions for summary judgment.

XV. EXPEDITED SCHEDULE

Genomic Health believes the case is ripe for expedited handling. Genomic Health does not challenge the validity of the Incyte patents. The only issues are the scope of a patent, and the legal effect of that scope and the patent's abandonment by Incyte under the LifeSeq Agreement to the genetic sequences detected by the Onco*type* DX® Breast Cancer Assay.

As noted above in Section VIII, Incyte does not believe that this case can be resolved using an expedited schedule and seeks broader discovery to fairly address the claims of both parties. Due to the manner by which the parties agreed, under the LifeSeq agreement, how and when royalty payments would be due and how much, Incyte must discover the details of Genomic Health's products and the manner by which they were developed. Incyte does not agree that the question of entitlement to royalties is necessarily limited to the Onco*type* DX® Breast Cancer Assay.

XVI. SCHEDULING

The parties propose that the Court adopt the following schedule based on the Federal Rules of Civil Procedure, Local Rules and applicable Standing Orders.

Event	Genomic Health's Proposed Date	Incyte's Proposed Date
Case Management Conference	**12/17/2010**	**12/17/2010**
Fact Discovery cut-off	**07/01/2011**	**9/30/2011**
Disclosure of Expert Reports [On issue party bears burden of proof]	**05/09/2011**	**12/02/2011**
Rebuttal Expert Report	**06/01/2011**	**1/13/2012**
Expert Discovery cut-off	**07/01/2011**	**2/10/2012**
Last Day to File Summary Judgment Motions	**09/02/2011**	**3/01/2012**
Trial (5 Days)	**To be scheduled at the Court's convenience**	**To be scheduled at the Court's convenience**

XVII. TRIAL

Genomic Health estimates that trial will require 5 days and requests that it be set as early as possible following resolution of summary judgment motions. At this point, before any discovery has been taken, Incyte estimates that trial will last 5 to 7 days.

XVIII. DISCLOSURE OF NON-PARTY INTERESTED ENTITIES OR PERSONS

Both parties have has filed the "Certification of Interested Entities or Persons" required by Civil Local Rule 3-16.

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP

Dated: December 10, 2010 By: /s/ William G. Gaede, III
William G. Gaede, III

Attorneys for Genomic Health, Inc.

WILMER CUTLER PICKERING
HALE AND DORR LLP

Dated: December 10, 2010 By: /s/ Mark D. Flanagan
Mark D. Flanagan

Attorneys for Incyte Corporation

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SIGNATURE ATTESTATION

Pursuant to General Order 45.X(B), I hereby attest that concurrence has been obtained from Mark D. Flanagan indicated by a "conformed" signature (/s/) within this e-filed document.

/s/ William G. Gaede, III
William G. Gaede, III